

[REDACTED]

Number/Name: P-18-0054/[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

SUMMARY INFORMATION

EPA estimated the human health hazard of this chemical substance based on its estimated physical/chemical properties and other structural information.

Based on the hazard determination and available quantitative risk information, EPA concludes that there is risk for the PMN substance. The risk can be mitigated by use of PPE.

Human Health Hazard:

- Expect poor absorption of the low molecular weight fractions [REDACTED].
- The polymer is [REDACTED] [REDACTED] which may result in developmental concerns. Based on average MW, this acid group would make up [REDACTED] of the PMN. If made differently, the acid group could make up a higher percentage of the PMN.
- **A LOAEL of 100 mg/kg/day was identified** based on fetal variations from a developmental toxicity study in rats for [REDACTED], which may form from the PMN.

Human Health Risk:

- Risks were identified for workers for developmental toxicity via dermal contact based on analogs (hydrolysis product) (MOE=476, Benchmark MOE=1000)
- Risks were not identified for workers for developmental toxicity via inhalation based on analogs (hydrolysis product) (MOE=5263, Benchmark MOE=1000).
- Risks were not identified for general population for developmental toxicity based on analog (hydrolysis product)) data (All MOEs>1000, Benchmark MOE=1000).

Potentially Useful Information:

- Potentially useful information would inform understanding of:
 - Developmental toxicity

PART A

SAT Date: 12/5/2017

SAT Chair: Tracy Behrsing/Kendra Moran

Health Assessor: Jocelyn Hospital

QC Reviewer: William Irwin, 12-8-17

Structure:

PMN: P-18-0054	Submitter:		Manu.	Import
Max. PV (KG):		Binding Option Marked:	X	X
MW:		% < 500		CASN
PMN Structure:		Prop.	Meas.	Est.
		MP		
		BP		>500
		Pres.		at 760 mm Hg
		VP		<0.000001
		S-H2O		<0.000001
		log P		
		Analogs:		
		other_uses		
		No other uses found.		

Polymer Exemption case (E1).

- CASRN:
- Chemical Category: None
- Chemical Category Health Concerns:
 - N/A
- Category Testing Strategy:
 - N/A
- PMN Health Rating:
 - 1-2

- **SAT Key Words:**
 - UNCERTAIN DEVEL
- **Absorption:**
 - Expect poor absorption of the low molecular weight fractions [REDACTED]
- **SAT Health Summary:**
 - The polymer is [REDACTED] [REDACTED] which may result in developmental concerns. Based on average MW, this acid group would make up [REDACTED] of the PMN. If made differently, the acid group could make up a higher percentage of the PMN.
- **PMN Data:**
 - None submitted.
- **Analog Data:**
 - No data identified for the following analogs:

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(38) ANALOGS:			
PMN or CAS No.	Chem. Name	Structure	TSCA Y/N
[REDACTED]			

- **Other Information:**
 - SDS
 - Irritation and sensitization possible.
- **Point of Departure Selected and Basis:**
 - A LOAEL of 100 mg/kg/day was identified based on variations in a developmental toxicity study in rats for [REDACTED] which may form from the PMN.

Exposure Routes of Interest:

- ☒ Inhalation
- ☒ Dermal:
- ☒ Ingestion

PART B

Focus Date:12/18/17

Focus Assessor: Baier-Anderson

QC:

USES and EXPOSURES:

- **Uses:** [REDACTED]
[REDACTED]
[REDACTED]
- **MSDS:**
 - Gen Eqpt: Hand protection: Use appropriate chemically resistant gloves as determined by an evaluation of glove performance characteristics and the hazards and potential hazards identified, including but not limited to butyl, natural and synthetic rubber, nitrile, or neoprene. // Eye protection: Wear face shield if splashing hazard exists. Tightly fitting safety goggles (chemical goggles). // Body protection: Body protection must be chosen based on level of activity and exposure. // General safety and hygiene measures: Work place should be equipped with a shower and an eye wash. Remove contaminated clothing. Contaminated equipment or clothing should be cleaned after each use or disposed of. Contact lenses should not be worn. Hands and/or face should be washed before breaks and at the end of the shift.
 - Respirator: Do not exceed the maximum use concentration for the respirator facepiece/cartridge combination. Observe OSHA regulations for respirator use (29 CFR 1910.134)
 - Health Effects: Skin corrosion/irritation. Serious eye damage/irritation. Skin Sensitization. Irritating to respiratory system.
- **Worker Exposure:**
 - Inhalation: [REDACTED] [REDACTED]
 - Dermal: [REDACTED] Potential Dose Rate: [REDACTED]
- **General Population Exposure:**
 - Based on human health hazard assessment and estimated releases, the PMN was evaluated for health routes of exposure
 - Adult general population exposure to the PMN chemical was estimated for
 - Drinking water ingestion with ADR as high as 2.25E-06 mg/kg/day and LADD as high as 7.52E-08 mg/kg/day
 - Inhalation from fugitive air releases with ADR as high as 2.50E-01 mg/kg/day
 - Exposure from predicted environmental fugitive air release(s) was not assessed for the chronic scenario

- Exposure from predicted environmental stack incineration release(s) was not assessed for the acute and chronic scenarios, as they are below modeling thresholds.
- Exposure from predicted environmental landfill release(s) was not assessed for the chronic scenario, as they are below modeling thresholds.
- Based on fate assessment, the PMN was not evaluated as persistent and bioaccumulative
- Based on production volume, the PMN was not evaluated as an exposure based case
- **Consumer Exposure:**
 - Consumer exposure to PMN chemical is not expected

RISK CALCULATIONS:

- **Worker Calculations:**
- Risks were identified for workers for developmental toxicity via dermal contact based on analogs (hydrolysis product) (MOE=476, Benchmark MOE=1000)
- Risks were not identified for workers for developmental toxicity via inhalation based on analogs (hydrolysis product) (MOE=5263, Benchmark MOE=1000).

Focus Worker Calculations MOE = (POD x Abs Rate) / ((PDR x Abs Rate) / BW) Acceptable MOE ≥100											
Exposure Scenarios and Values ¹	POD= N/LOAEL (mg/kg/day)	POD Route Absorp . Adj ²		Potential Dose Rate (mg/day)	Exposure Route Absorp Adj ²	Structural Alert/ Component as % of PMN		Avg BW ³ All Adults, 80 (kg)		Margin of Exposure ⁴ (POD/PMN Dose)	Inhalation Fold" Factor ⁵ (Benchmark/ MOE)
WORKER RISK											
Highest/Worst Case Doses from Engineering Report											(LOAEL=1000)
Inhalation	(100	x 100%) ÷ (x 100%	x		÷ 80) =	5263	0.2
Dermal	(100	x 100%) ÷ (x 15%	x		÷ 80) =	476	N/A

¹ Inhalation doses in mg/day are from the Engineering Report generated using ChemSTEER. Unless otherwise stated, the assumption is an 8-hr day. The EPA/OPPT 2-Hands Dermal Contact with Liquids Model calculates worker dermal exposures to a liquid. Model assumptions are: (1) surface area of contact equals two hands (1,070 cm²); (2) high-end default value of quantity remaining on skin = 2.1 mg/cm² (low-end default = 0.7 mg/cm²); (3) weight fraction of chemical in liquid; (4) 1 contact/worker-day; (5) no use of controls or gloves to reduce exposure; (6) exposure duration = 1 to 4 hours based expectation that worker will, at a minimum, thoroughly wash hands at lunch or end of the day.

² Absorption adjustments for Focus - Assume 100% for POD; For Exposure. If risks, consider adjustments for absorption, etc.

³ USEPA 2011. Exposure factors handbook, final report, EPA/600-R09/052F, 2011, Chapter 8 Body Weight Studies, Table 8-1, Recommended Values for Body Weight <http://www.epa.gov/ncea/efh/pdfs/efh-chapter08.pdf>

⁴ Benchmark (Acceptable) MOEs are 100 for NOAEL-based assessment and 1000 for LOAEL-based assessment.

⁵ Fold factor = value to be applied to bring INHALATION MOE up to acceptable level, used by the CEB Industrial Hygienist to determine respirator recommendations. NOAEL-based fold factor = 100/MOE; LOAEL-based fold factor = 1000/MOE.

- **General Population Calculations**
- Risks were not identified for general population for developmental toxicity based on analog (degradant) data (All MOEs>1000, Benchmark MOE=1000).

Focus General Population MOE Calculations												
MOE = (POD x Abs Rate) / ((PDR x Abs Rate) / BW) Benchmark (acceptable) MOE ≥100												
Exposure Scenarios and Values ¹	POD= LOAEL (mg/kg/day)		POD Route Absorp Adj ²			Exposure Acute Dose Rate (mg/kg/day)		Exposure Route Absorp Adj ²		Multiplier for Sensitive Sub-populations ⁴		Structural Alert/ Component as % of PMN
GENERAL POPULATION RISK												
Highest/Worst Case Doses from Exposure Report												(LOAEL=1000)
Drinking Water	(100	x	100%) ÷ (x	100%	x	1.00	x) = 1111111111
Drinking Water	(100	x	100%) ÷ (x	100%	x	4.17	x) = 266453504
Fish Ingestion	(100	x	100%) ÷ (x	100%	x	1.00	x) = 10000
¹ General Population and Consumer ingestion Acute Dose Rates are from the Exposure Report and are generated using E-FAST which assumes a 100% absorption rate, and uses an average adult body weight of 80 kg. Consumer ADRs are generated using the Consumer Exposure Module within the E-FAST CBI version called "NCEM2" model. ² Absorption adjustments for Focus: Assume 100% POD; if risks, consider adjusting for absorption, etc. ³ Benchmark (Acceptable) MOEs are 100 for NOAEL-based assessment and 1000 for LOAEL-based assessment. ⁴ Multiplier based on increased drinking water consumption for infants. Multiplier would be less for older populations, so this value is worst-case.												

- **Consumer Calculations:**
 - Consumer risks were not evaluated because consumer use was not identified as a condition of use.